MEDICAL MUTUAL®

Drug Policy

Policy:	Rhapsido® (remibrutinib tablets – Novartis)	Annual Review Date: 05/21/2026 Last Revised Date: 05/21/2026

OVERVIEW

Rhapsido, a Bruton's kinase (BTK) inhibitor, is indicated for **chronic spontaneous urticaria** (CSU) in adults who remain symptomatic despite H_1 antihistamine treatment.[1] Limitation of use: Rhapsido is not indicated for other forms of urticaria.

POLICY STATEMENT

This policy involves the use of Rhapsido. Prior authorization is recommended for pharmacy benefit coverage of Rhapsido. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Rhapsido as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Rhapsido be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Rhapsido is recommended in those who meet the following criteria:

1. **Chronic Spontaneous Urticaria.** Approve Rhapsido for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii and iv):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has/had urticaria for ≥ 6 weeks (prior to treatment with Rhapsido); AND
     - **iii.** According to the prescriber, the patient has tried high-dose oral second-generation H_1 antihistamine therapy; AND
       Note: High-dose oral second-generation H_1 antihistamine therapy is the highest dose tolerated by the patient and can be up to four times the FDA-approved dose. Examples of second-generation H_1 antihistamines are cetirizine, desloratadine, fexofenadine, levocetirizine, and loratadine.
     - **iv.** The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist; OR
   - **B)** Patient is Currently Receiving Rhapsido. Approve Rhapsido for 1 year if the patient meets BOTH the following criteria (i and ii):
     - **i.** Patient has already received at least 6 months of therapy with Rhapsido; AND

Note: A patient who has received < 6 months of therapy or who is restarting therapy with Rhapsido should be considered under criterion 1A (Chronic Spontaneous Urticaria, Initial Therapy).

ii. Patient has experienced a beneficial clinical response, defined by ONE of the following (a, b, or c):
- **a)** Decreased itch severity; OR
- **b)** Decreased number of hives; OR
- **c)** Decreased size of hives

Initial Approval/ Extended Approval.
A) *Initial Approval:* 6 months
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Rhapsido has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Rhapsido® tablets [prescribing information]. East Hanover, NJ: Novartis; September 2025.
2. Zuberbier T, Abdul Latiff AH, Abuzakouk M, et al. The international EAACI/GA^{2}LEN/EuroGuiDerm/APAAACI guideline for the definition, classification, diagnosis, and management of urticaria. *Allergy.* 2022;73:734-766.